Supreme Court, U.S.
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No. _____

In The

Supreme Court of the United States

October Term, 1996

ARGENT CHEMICAL LABORATORIES, INC., various articles of drug identified in Attachment A, which are located at Argent Chemical Laboratories, Inc., 8515 and 8702 152nd Avenue N.E. Redmond, Washington,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Did the Ninth Circuit err when it held that the use of a non-judicial arrest warrant was necessary to further the regulatory scheme of the Food, Drug and Cosmetic Act?

2. Is the use of a non-judicial arrest warrant improper when the seizure is not conducted contemporaneously with an administrative search and there is no showing of an immediate threat to the public or other exigent circumstances?

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The opinion of the United States Court of Appeals for the Ninth Circuit that gives rise to this Petition is reported at 93 F.3d 572 (9th Cir. 1996). It is reprinted in Appendix A hereto ("App. A") at Page A-1.

The Order of the District Court for the Western District of Washington which granted petitioner's motion to quash is unpublished and may be cited as No. C94-1120C (W.D. Wash. Oct. 15, 1994) (Order granting Motion to Quash Warrant and Return Property). It is reprinted in Appendix B hereto ("App. B") at page B-1.

JURISDICTION

Petitioner seeks review of the United States Court of Appeals for the Ninth Circuit's decision filed on August 16, 1996. In that decision, the Ninth Circuit reversed the order of the United States District Court for the Western District of Washington quashing a Warrant for Arrest *In Rem* which permitted the seizure from petitioner of various veterinary drug products. Pursuant to Supreme Court Rule 13.1, this petition has been filed within 90 days of the entry of judgment.

The jurisdiction of the Court is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTES AND CONSTITUTIONAL PROVISIONS INVOLVED IN THIS CASE

21 U.S.C. § 334. The text of § 334 is reprinted in Appendix C hereto ("App. C") at page C-1.

Supplemental Rules for Certain Admiralty and Maritime Claims, Rule C. The text of Rule C is reprinted in Appendix D hereto ("App. D") at page D-1.

The Fourth Amendment to the United States Constitution provides:

> The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

I. STATEMENT OF THE CASE

Petitioner, Argent Chemical Laboratory ("Argent"), manufactures veterinary drug products. Agents of the Food and Drug Administration ("FDA") inspected Argent Chemical Laboratory facilities on May 9, 1994. The FDA cited Argent for certain violations of the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("the Act"), and asked that corrections be made. The FDA did not take any enforcement action at the time of the May 9, 1994 inspection and made no attempt to seize drugs at that time. The FDA did not order Argent to stop manufacturing drugs, nor did it order Argent to cease selling the drugs that it had already manufactured.

Argent continued to manufacture and sell its products and made the corrections which the FDA had requested. Each of the FDA's concerns were addressed by the management of Argent and either corrections were made or explanations were given to the FDA. Throughout the summer of 1994, the FDA gave Argent no indication that its efforts failed to bring it in compliance with the Act.

On July 29, 1994, almost three months after its most recent inspection, the FDA filed a complaint in the Western District of Washington for the forfeiture of several categories of veterinary drugs and their constituent materials in Argent's possession. The FDA then obtained a warrant for arrest *in rem* in order to seize those drugs. The warrant was not issued by a magistrate, but by Nealann Shari, a deputy clerk of the District Court. Argent was not given notice of the complaint, nor of the warrant for arrest. Then on August 11, 1994, 13 days after the warrant was issued and 94 days after the FDA's last inspection, federal agents entered Argent's place of business and seized over $100,000 worth of chemicals.

The warrant for arrest *in rem* was issued pursuant to the Act, 21 U.S.C. § 334(b), which permits the seizure of articles under the procedure in admiralty provided in Rule C of the Supplemental Rules for Certain Admiralty and Maritime Claims (Rule C). Rule C does not require a showing of probable cause, nor review by a magistrate, but instead allows a court clerk to issue a warrant of arrest upon the filing of a complaint.

The district court granted Argent's motion to quash the warrant finding that the warrant violated the Fourth Amendment. The district court noted that although the Court has carved out an exception to the Fourth Amendment which allows inspections of "closely regulated" industries, the exception applies only to administrative inspections. App. B. The district court held that the exception did not allow the government to "conduct a particularized search and seizure without first obtaining an ordinary warrant." App. B.

The government appealed and the Ninth Circuit reversed. The Circuit Court held that the *Colonnade-Biswell* exception which allows warrantless administrative inspections of "closely regulated businesses" also allows the government to conduct particularized warrantless searches for the purpose of seizing evidence.

II. ARGUMENT

A. The Ninth Circuit Erred When it Found that the Seizure of Argent's Property Pursuant to a Non-Judicial Warrant Was Necessary to Further the Regulatory Scheme of the Food, Drug & Cosmetic Act.

This forfeiture action arose under 21 U.S.C. § 334, which authorizes the seizure and forfeiture of, among other things, adulterated drugs. The statute provides that "the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty." § 334(b).

Rule C of the Supplemental Rules for Certain Admiralty and Maritime Claims provides that:

> [I]n actions by the United States for forfeitures for federal statutory violations, the clerk, upon filing of the complaint, shall forthwith issue a summons and warrant for the arrest of the vessel or other property without requiring a certification of exigent circumstances.

It is a fundamental proposition of Fourth Amendment law that "except in certain carefully defined classes of cases, a search of private property without proper consent is 'unreasonable' unless it has been authorized by a valid search warrant." *Camara v. Municipal Court*, 387 U.S. 523, 529 (1967). A valid search warrant requires a showing of probable cause and review by a neutral and impartial magistrate. *Horton v. California*, 496 U.S. 128, 143 (1990) (Brennan, J., dissenting). Rule C violates fundamental Fourth Amendment law because it does not require a showing of probable cause, nor scrutiny by an impartial magistrate, and it does not fit within any of the narrow exceptions to the warrant requirement.

This Court has carved out exceptions to the warrant requirement for "pervasively regulated businesses" and for "closely regulated industries long subject to close supervision and inspection." *Marshall v. Barlow's, Inc.*, 436 U.S. 307, 313 (1978). In *Colonnade Catering Corp. v. United States*, the Court acknowledged Congress' "broad authority to fashion standards of reasonableness for searches and seizures" in the liquor industry "long subject to close supervision and inspection." 397 U.S. 72, 77 (1970). Then, in *United States v. Biswell*, 406 U.S. 311, 317 (1972), the Court held that warrantless inspections of a firearms dealership, conducted pursuant to a statutory inspection scheme, did not offend the Fourth Amendment.

More recently, the Court has upheld warrantless inspection schemes involving coal mines, *Donovan v. Dewey*, 452 U.S. 594 (1981), and automobile junkyards, *New York v. Burger*, 482 U.S. 691 (1987).

In *Burger*, the Court clarified that warrantless inspections of pervasively regulated businesses are reasonable only if three criteria are met. First, there must be a substantial government interest that informs the regulatory scheme. *Id.* at 702. Second, the warrantless inspections must be necessary to further the regulatory scheme. *Id.* at 702-03. And third, the inspection program, in terms of the certainty and regularity of its application, must provide a constitutionally adequate substitute for a warrant. *Id.* at 703.

In the present case, the Ninth Circuit held that the *Colonnade-Biswell* exception to the warrant requirement applied to the Argent seizure. Specifically, the Ninth Circuit held that the drug-manufacturing industry is so closely regulated that owners of drug factories have a lesser expectation of privacy which must give way to the government's substantial interest in protecting the public from adulterated drugs. Therefore, the Ninth Circuit reasoned, the *in rem* arrest procedure of Supplemental Rule C does not violate any Fourth Amendment protection afforded the owners of a veterinary drug manufacturing company.

The Ninth Circuit's analysis, however, failed to adequately consider the criteria set forth in *Burger*, 482 U.S. at 702-03, and failed to properly limit the administrative inspection exception.

The court in *Burger*, recognized that there must be limits on administrative inspections. A procedure that circumvents the Fourth Amendment warrant requirement should be permitted only when it is "necessary" to further a regulatory scheme. Here, there was no showing that a non-judicial arrest warrant procedure was necessary to further the regulatory scheme. There was no showing that the government's interest would have been impaired by obtaining a warrant from a judge or magistrate. There was no showing of an imminent danger to the public that would justify using a non-judicial warrant of arrest.

The provisions of § 334 which permit warrants of arrest issued by court clerks instead of judicially scrutinized seizure warrants based on probable cause are unnecessary to the regulatory scheme. Under the criteria of the *Burger* decision, the seizure provisions of Rule C violate the Fourth Amendment because they are unnecessary.

The Ninth Circuit's analysis failed to distinguish between regulatory inspections and later, particularized seizures of property at the same location. While the regulatory inspections may have been necessary to further the regulatory scheme, the non-judicial warrant procedure used in the later particularized seizure of property was not necessary. There was no showing that the Rule C non-judicial warrant provisions were important or necessary to the regulatory scheme.

In the present case, the FDA waited 94 days after the last regulatory inspection before taking any action to seize Argent's property. There was no showing that the

FDA would have been hindered in its seizure of Argent's property by forcing the agency to obtain a traditional seizure warrant. The FDA should have obtained a warrant from a neutral magistrate upon a showing of probable cause before seizing Argent's property on August 11, 1994.

B. The Ninth Circuit's Decision in the Argent Case Directly Conflicts With an Earlier Ninth Circuit Decision, a Prior District Court Opinion, and the Tenth Circuit's Holding in *S & S Pawn Shop, Inc. v. City of Del City*.

An earlier Ninth Circuit decision addressed the issue of whether a court clerk may, consistent with the Fourth Amendment, issue a warrant for an arrest *in rem* under § 334. In *United States v. Device, Labeled "Theramatic"*, 641 F.2d 1289 (9th Cir. 1981), federal agents entered a doctor's office and seized a diathermy machine alleged to be misbranded. The agents acted on the authority of an arrest warrant issued by the clerk of the court. The Ninth Circuit concluded:

> We hold that absent exigent circumstances, entrance into homes and offices to seize items alleged to violate the Food, Drug, and Cosmetic Act must comply with the basic requirements of the Fourth Amendment: the verified complaint on which the warrant authorizing seizure is based must provide probable cause to believe that the article to be seized violates the act, and the complaint must be scrutinized by a detached, independent official, empowered to decide whether probable cause does exist, before the warrant is issued.

Id. at 1295. In so holding, the court explained that because "the government has a specific target in mind," the cases involving random inspections to enforce statutory standards did not apply. *Id.* at 1294. *Theramatic* did not address the question of whether the general inspection scheme of the Act violated the Fourth Amendment, the constitutionality of which would be subject to analysis under *Colonnade-Biswell*. Instead, *Theramatic* addressed whether *in rem* arrest warrants may constitutionally be issued pursuant to § 334 and Supplemental Rule C. Although a well-defined scheme for inspecting pervasively regulated businesses may survive Fourth Amendment scrutiny, the protection against unreasonable searches and seizures may nevertheless prevent government agents from returning to conduct a particularized search and seizure without first obtaining an ordinary warrant. *See Coolidge v. New Hampshire*, 403 U.S. 443, 471-72 (1971) (holding "plain view" exception did not apply to seizure of car when police knew of car's location, intended to seize the car, and had ample opportunity to obtain warrant).

The agents in this case had previously conducted administrative inspections pursuant to § 374(a) of the Act. The constitutionality of these inspections is not an issue here. Based on their conclusion that Argent was in violation of the Act, the agents obtained the *in rem* arrest warrant to search a particular business to seize particular, identified chemicals and drugs. The arrest warrant was issued, pursuant to § 334 and Supplemental Rule C, by a deputy clerk who did not review the government's allegations to determine if there was cause to seize the items.

This is precisely what the Ninth Circuit forbade in *Theramatic*.

Other courts have made the distinction between routine administrative inspections and seizures of particular, identified items. In *United States v. Articles of Drug . . . Neptone*, 569 F. Supp. 1182 (N.D. Cal. 1983) the court found that an FDA seizure violated the Fourth Amendment when it seized drugs without a warrant:

> Whether Aquaculture reasonably expected the Hirschberg facilities to be subject to regular government inspection is irrelevant here, as the act in question was a premeditated seizure of specified items . . . it is well settled that where it is practicable to obtain a warrant, the government must do so. Indeed, where the government knows in advance the location and description of evidence and intends to seize it, as was the case here, the requirement of a warrant imposes no constitutionally recognizable inconvenience . . . . Here there is no evidence of any exceptional situation that would justify a warrantless seizure. The government does not contend that it was responding to an emergency or that it was in hot pursuit. There is no evidence that the goods were being destroyed or were about to be removed from the premises. The government offers no evidence that it was impracticable to obtain a warrant. (citations omitted)

The court in *Neptone* recognized that portions of an administrative inspection scheme may be unconstitutional if they are unnecessary to further the regulatory scheme. Warrantless searches to seize particularized pieces of evidence, absent a showing of exigent circumstances, are unnecessary.

The Ninth Circuit's decision in *Argent* also conflicts with the Tenth Circuit holding in *S & S Pawn Shop, Inc. v. City of Del City*, 947 F.2d 432 (10th Cir. 1991). In that case, the court found that the pawn shop business was closely regulated justifying warrantless administrative inspections. The court found, however, that some searches and seizures of *S & S Pawn* may have been conducted pursuant to "direct criminal suspicion," thus necessitating a warrant:

> As evidenced in the depositions, appellant presents material facts demonstrating that the inspections of appellant's business premises were conducted not as part of a pre-planned and dispassionate administrative procedure but instead pursuant to direct criminal suspicion. Such a search gives cause for grave constitutional concern. A proper administrative search is conducted on neutral criteria to restrain the discretion of the officer in charge of the search.

The Tenth Circuit does not permit warrantless searches of highly regulated businesses when the search is being conducted for a particular item as evidence of a crime. In *Winters v. Board of County Commissioners*, 4 F.3d 848 (9th Cir. 1993), the police had entered a pawnshop solely for the purpose of seizing evidence of a crime that the police knew was in possession of the pawnshop. The Tenth Circuit found that pawnshops are "closely regulated" industries under Oklahoma law for the purposes of the *Colonnade-Biswell* exception. *Id.* at 852 (citing *S.S. Pawn*, 947 F.2d at 436-39). However, the court did not allow the government to bootstrap the police's entrance into the pawnshop to seize particular property onto the

government's ability to administratively inspect the pawnshop:

> If we were to allow an officer under the guise of the administrative statute to seize evidence of criminal activity without a warrant when the officer has a particularized suspicion regarding that evidence, we would eradicate the Fourth Amendment protections enjoyed by the pawnshop.
>
> Although we upheld the constitutionality of the Oklahoma statutes in *S & S Pawn*, we cautioned that the execution of an administrative search pursuant to direct criminal suspicion raises grave constitutional concerns. *S & S Pawn* 947 F.2d at 441. We noted that the exigent circumstances allowing a warrantless administrative search evaporate when the police intend to seize particular criminal evidence. "Once it is discovered that a pawnshop possesses stolen property, 'spot' searches are no longer necessary. Moreover, after the pawn tickets are turned over to the enforcing officer, 'surprise' no longer appears to justify the necessity of a warrantless search." *Id.* at 441 n.7. Simply put, when a law enforcement officer intends to seize a particular piece of criminal evidence from the premises of a pawnshop, the seizure may not be substantiated by relying on the pretense of an administrative search coupled with the plain view doctrine. In such a situation, the officer must obtain a warrant. Thus we reverse the district court and find there was a seizure in violation of Ms. Winter's Fourth Amendment rights.

Id. at 854-55.

The reasoning of the Tenth Circuit in *S & S Pawn* and *Winters* is in direct conflict with the Ninth Circuit's

decision in Argent when applying the *Colonnade-Biswell* exception. The conflict is irreconcilable and certiorari is appropriate.

III. CONCLUSION

The Court should accept review of the Ninth Circuit decision both because the lower court misapplied the *Colonnade-Biswell* exception to the warrant requirement and because the decision conflicts with decisions within the Ninth Circuit and also with the Tenth Circuit's application of the *Colonnade-Biswell* exception when the government enters a "closely regulated" business not to inspect, but for the sole purpose of seizing property.

Respectfully submitted this 13th day of November, 1996.

FINEGOLD & ZULAUF

JON R. ZULAUF
Attorney for Argent Chemical Laboratories, Inc.

No. _____

In The

Supreme Court of the United States

October Term, 1996

ARGENT CHEMICAL LABORATORIES, INC., various articles of drug identified in Attachment A, which are located at Argent Chemical Laboratories, Inc., 8515 and 8702 152nd Avenue N.E. Redmond, Washington,

Petitioner,

v.

UNITED STATES OF AMERICA,

Respondent.

Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

APPENDIX

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

UNITED STATES OF AMERICA, *Plaintiff-Appellant,* v. ARGENT CHEMICAL LABORATORIES, INC., various articles of drug identified in Attachment A, which are located at Argent Chemical Laboratories, Inc., 8515 and 8702 152nd Avenue NE, Redmond, Washington, *Defendant-Appellee.*	No. 95-35167 D.C. No. CV-94-01120-JCC OPINION

Appeal from the United States District Court
for the Western District of Washington
John C. Coughenour, District Judge, Presiding

Argued and Submitted
January 9, 1996 – Seattle, Washington

Filed August 16, 1996

Before: James R. Browning, Eugene A. Wright and
William C. Canby, Jr., Circuit Judges

Opinion by Judge Canby

COUNSEL

Jacob M. Lewis, United States Department of Justice, Washington, D.C., for the plaintiff-appellant.

John R. Zulauf, Finegold, Zulauf & Engelhard, Seattle, Washington, for the defendant-appellee.

OPINION

CANBY, Circuit Judge:

Under procedures authorized by Congress, the Food and Drug Administration ("FDA") seized allegedly adulterated products from the premises of a regulated veterinary drug manufacturer, without obtaining a warrant from a judicial officer issued upon a finding of probable cause. The question before us is whether that seizure violated the Fourth Amendment. We concluded that it did not, and we reverse the judgment of the district court.

I. The Factual Background

Argent Chemical Laboratories manufactures and repackages veterinary drugs. FDA agents inspected Argent several times between the summer of 1993 and May 1994 to ensure compliance with the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("Act"). The FDA cited Argent for certain deficiencies. Several months after the last inspection, the FDA agents secured from the

Deputy Clerk of the District Court, without the intervention of a judicial officer or a showing of probable cause, an *in rem* arrest warrant for various veterinary drugs alleged to violate the Act. FDA agents and United States Marshals then seized over $100,000 worth of veterinary drugs from Argent's premises.

This condemnation action followed. Argent appeared as claimant and contested the constitutionality of the seizure. The district court held that the seizure violated the Fourth Amendment; it accordingly granted Argent's motion to quash the *in rem* arrest warrant and ordered the government to return the property. The government appealed, and the district court stayed its order pending the appeal.

II. The Statutory Scheme of Seizure

The warrant in this case was issued in accordance with the Act. Under the Act, an article "proceeded against shall be liable to seizure by process pursuant to the libel, and the procedures in cases under this section shall conform, as nearly as may be, to the procedure in admiralty. . . . " 21 U.S.C. § 334(b). Under the Supplemental Rules for Certain Admiralty and Maritime Claims ("Supplemental Rules"), an *in rem* action begins with a complaint that must "be verified on oath or solemn affirmation" and that must "describe with reasonable particularity the property that is the subject of the action." Supplemental Rule C(2). Upon filing of the complaint, the clerk issues a warrant:

> Except in actions by the United States for forfeitures for federal statutory violations, the verified complaint and any supporting papers shall be reviewed by the court and, if the conditions for an action in rem appear to exist, an order so stating and authorizing a warrant for the arrest of the vessel or other property that is the subject of the action shall issue and be delivered to the clerk who shall prepare the warrant.
>
> . . .
>
> *In actions by the United States for forfeitures for federal statutory violations, the clerk, upon filing of the complaint, shall forthwith issue a summons and warrant for the arrest of the vessel or other property.*
>
> . . .

Supplemental Rule C(3) (emphasis added). Thus, because this was an action by the United States for a forfeiture for federal statutory violations, FDA agents were able to obtain a warrant without review by a judicial officer or a finding of probable cause.

III. The Fourth Amendment and the *Colonnade-Biswell* Exception

Argent argues that, although the drugs were seized pursuant to a warrant issued in accordance with the Act, the seizure violated the Fourth Amendment's prohibition of unreasonable searches and seizures and its requirement that warrants issue upon probable cause. We conclude, however, that Argent's argument is defeated by the nature of its business and the regulation to which it is subject.

The Fourth Amendment applies to commercial premises as well as to private homes, *See v. City of Seattle*, 387 U.S. 541, 546 (1967), but under the so-called *Colonnade-Biswell* exception, warrantless searches and seizures on commercial property used in "closely regulated" industries are constitutionally permissible. *Colonnade Catering Corp. v. United States*, 397 U.S. 72 (1970); *United States v. Biswell*, 406 U.S. 311 (1972). Persons engaging in pervasively regulated industries have a diminished expectation of privacy. *New York v. Burger*, 482 U.S. 691, 702 (1987); *Biswell*, 406 U.S. at 316. With regard to such industries, "Congress has broad authority to fashion standards of reasonableness for searches and seizures." *Colonnade*, 397 U.S. at 77. Thus in *Colonnade* and *Biswell*, the Court held that there was no constitutional violation when the businesses of dispensing liquor and selling firearms, respectively, were subjected to inspections and seizures without a warrant issued by a judicial officer upon probable cause.

Argent asserts that it is not subject to the *Colonnade-Biswell* exception for two reasons: first, its veterinary drug business is not the kind of industry that is subject to the *Colonnade-Biswell* exception; and second, the *Colonnade-Biswell* exception does not extend to a separate and particularized seizure of misbranded or adulterated goods. We reject both contentions.

IV. Manufacture of Veterinary Drugs as a Closely Regulated Industry

In *New York v. Burger*, 482 U.S. at 702-03, the Supreme Court set forth the standards for determining when the

Colonnade-Biswell exception applies.[1] A warrantless inspection will be deemed reasonable only if the business is closely regulated and if three criteria are met:

> First, there must be a "substantial" government interest that informs the regulatory scheme pursuant to which the inspection is made. . . .
>
> Second, the warrantless inspections must be "necessary to further [the] regulatory scheme." . . .
>
> Finally, "the statute's inspection program, in terms of the certainty and regularity of its application, [must] provid[e] a constitutionally adequate substitute for a warrant."

Burger, 482 U.S. at 702-03 (quoting *Donovan v. Dewey*, 452 U.S. 594, 600, 602-03 (1981)). We conclude that all of these standards are met in this case.

As a threshold matter, the veterinary drug industry is "closely regulated." *See generally* 21 U.S.C. §§ 301 - 392; 21 C.F.R. Pts. 200-599. The Food, Drug, and Cosmetic Act prohibits the adulteration or misbranding of any drug, 21 U.S.C. § 331(b), whether that drug is intended for use by either humans or animals, 21 U.S.C. § 321(g)(1)(B). "[V]irtually every phase of the drug industry is heavily regulated, from packaging, labeling, and certification of expiration dates, to prior FDA approval before new drugs

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[1] Although *Burger* pertained only to a search, the *Colonnade-Biswell* exception applies to searches and seizures. *See Colonnade*, 397 U.S. at 77 (warrantless search and seizure of liquor held constitutional); *Biswell*, 406 U.S. at 317 (warrantless search and seizure of firearms held constitutional); *see also infra* part III.

can be marketed." *United States v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 537 (8th Cir. 1981) (footnotes omitted), *cert. denied*, 455 U.S. 1016 (1982); *see e.g.*, 21 U.S.C. § 351(a) (regulating manufacture), § 351(b) (regulating strength, quality, and purity), § 352(a), (b), (f). (g), (h), (p), regulating packaging and labeling); § 355 (new drug approvals), § 360b (regulating new animal drug approvals). Regulations implementing the act are quite extensive. *See generally* 21 C.F.R. Pts. 200-599. For example, good manufacturing practices for the preparation of human and animal drugs are set forth in detail. *See* 21 C.F.R. Pts. 210, 211.[2] The veterinary drug industry is certainly regulated as extensively as the vehicle dismantling industry, which the Supreme Court has held to be "closely regulated." *See Burger*, 482 U.S. 703-04.

Although duration of a particular regulatory scheme has "some relevancy" in determining whether an industry is closely regulated, *Burger*, 482 U.S. at 705, "it is the pervasiveness and regularity of the federal regulation that ultimately determines whether a warrant is necessary." *Donovan*, 452 U.S. at 606. The pervasiveness and regularity of the current regulatory scheme is sufficient to

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[2] These regulations include personnel qualifications and responsibilities, 21 C.F.R. §§ 211.25, 211.28; buildings and facilities specifications, 21 C.F.R. §§ 211.42-211.58; equipment specifications, 21 C.F.R. §§ 211.63-211.72; production and process controls, 21 C.F.R. §§ 211.100-211.115; packaging and labeling controls, 21 C.F.R. §§ 211.122-211.137; holding and distribution procedures, 21 C.F.R. §§ 211.142, 211.150; laboratory controls, 21 C.F.R. §§ 211.160-211.176; and requirements for recording and reporting, 21 C.F.R. §§ 211.180-211.198, to name but a few.

make it "closely regulated" under *Burger* wholly apart from any consideration of duration.[3]

FDA regulation of Argent's industry also meets the three enumerated criteria of *Burger*. First, there is "a 'substantial' government interest that informs the regulatory scheme pursuant to which the inspection is made." *Burger*, 482 U.S. at 702. Argent argues that in some respects animal drug provisions are less stringent than human drug provisions, *compare* 21 U.S.C. § 355 (new drugs) *with* 21 U.S.C. § 360b (new animal drugs), and that regulation of animal drugs is primarily motivated by economic considerations rather than human safety, *see* 1 James T. O'Reilly, *Food and Drug Administration* § 16.01, at 16-3 & n.9 (2d ed. 1995). Neither argument suggests that the government lacks a substantial interest in ensuring the safety and effectiveness of animal drugs. Congress has seen fit, either for human safety or for economic reasons, to regulate animal drugs to ensure their safety and effectiveness. Whether the interest is human health, economic health, or both, we conclude that it is substantial.

Second, "the warrantless inspections [are] 'necessary to further [the] regulatory scheme.' " *Burger*, 482 U.S. at 702 (quoting *Donovan*, 452 U.S. at 600). Unannounced inspections have a deterrent effect; forcing inspectors to obtain a warrant before inspection might frustrate the purpose of the Act by alerting owners to inspections. *See id.* at 702-03; *Biswell*, 406 U.S. at 316. Moreover, this court

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[3] We note, however, that the original 1906 Food and Drugs Act provided for regulation of animal drugs. Act of June 30, 1906, ch. 3915, § 6, 34 Stat. 769.

has recognized the "need for swift governmental action to remove misbranded products from the stream of commerce." *United States v. An Article of Device "Theramatic"*, 715 F.2d 1339, 1343 (9th Cir. 1983) (*"Theramatic II"*), *cert. denied sub nom. Cloward v. United States*, 465 U.S. 1025 (1984). Thus, warrantless searches and seizures are necessary to further the regulatory scheme that ensures the integrity of veterinary drugs.

Finally, the regulatory scheme, " 'in terms of the certainty and regularity of its application, [provides] a constitutionally adequate substitute for a warrant,' " thereby satisfying the third *Burger* requirement. *Burger*, 482 U.S. at 703 (quoting *Donovan*, 452 U.S. at 603). "[T]he regulatory statute must perform the two basic functions of a warrant: it must advise the owner of the commercial premises that the search is being made pursuant to the law and has a properly defined scope, and it must limit the discretion of the inspecting officers." *Id.* Taken as a whole, the Act, the accompanying regulations, and the Supplemental Rules for Certain Admiralty and Maritime Claims provide a constitutionally adequate substitute for a warrant. Inspections are conducted with notice furnished at the time, and their scope is limited by statute. 21 U.S.C. § 374(a)(1). Seizures are limited to drugs that are adulterated or misbranded, 21 U.S.C. § 334(a)(1), the articles to be seized must be described "with reasonable particularity," Supplemental Rules C(2), and the government's complaint must be "verified on oath or solemn affirmation," *id.* Moreover, in most cases, the seizure is subject to the approval of one of the Food and Drug Administration's district offices, the appropriate office (or "center") in the Food and Drug Administration headquarters, the

Food and Drug Administration's Office of Enforcement, the Office of the Chief Counsel, and the Department of Justice. *See FDA Regulatory Procedures Manual*, ch. 6, at 173-85 (Aug. 1995).[4]

We conclude, therefore, that Argent's operation, as regulated by the FDA, falls within the *Colonnade-Biswell* exception to the Fourth Amendment's warrant requirement.

V. The Particularized Seizure and the Warrant Requirement of the *Theramatic* Case

Argent next contends that, even if it is a "closely regulated" industry for purposes of the *Colonnade-Biswell* exception, that exception does not apply to the seizure in this case.

To the extent that Argent's argument suggests that the *Colonnade-Biswell* exception applies only to inspections and not to seizures, the argument is untenable. It is true that *Burger* discussed its criteria for "closely regulated" industries in terms of "inspections," but it also approved the use of evidence seized in the course of the inspection. 482 U.S. at 716. Moreover, both *Colonnade* and *Biswell* involved seizures of contraband discovered during the unwarranted inspections. *Biswell* held that, because the unwarranted inspection was constitutionally permissible. "[t]he seizure of respondent's sawed-off

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[4] On occasion, in the case of so-called "direct reference seizures," headquarters review is skipped. *See FDA Regulatory Procedures Manual*, ch. 6, at 176.

rifles was not unreasonable under the Fourth Amendment." 406 U.S. at 317. Thus, *Colonnade-Biswell* extends to seizure without warrant of what may be inspected without warrant, when Congress so authorizes.

The argument that Argent most vigorously asserts, and the one that was accepted by the district court, is based on our decision in *United States v. Device Labeled "Theramatic"*, 641 F.2d 1289 (9th Cir. 1981) (*"Theramatic I"*), In *Theramatic I*, we held that the Fourth Amendment was violated by the FDA's seizure from a physician's office of an allegedly misbranded medical device pursuant to a warrant issued under the Supplemental Rules. *Id.* at 1295. We emphasized that the physician was entitled to the protection of the Fourth Amendment in his office just as he was in his home. *Id.* at 1292. We recognized that some administrative searches could be conducted on the strength of a warrant issued on less than probable cause, but the government in *Theramatic I* was not conducting random inspections to enforce administrative standards; it was "searching a particular physician's office to seize a particular, identified device." *Id.* at 1294. Finally, we said that the *Colonnade-Biswell* exception to the warrant requirement did not apply because the "search at issue here was not part of any statutory program to inspect physicians' offices." *Id.* at 1295.

We do not draw from *Theramatic I* the same lessons that Argent and the district court did. The problem with the seizure in *Theramatic I* was that it was effectuated by an impermissible invasion of the physician's right of privacy. That is why we were careful in *Theramatic I* to point out that the case involved not only a seizure, "but a paradigmatic search – a physical intrusion by the U.S.

Marshal into [the physician's] office." *Id.* at 1291. We also stated:

> It is one thing to seize without a warrant property resting in an open area or seizable by levy without an intrusion into privacy, and it is quite another thing to effect a warrantless seizure of property, even that owned by a corporation, situated on private premises *to which access is not otherwise available for the seizing officer.*

Id. at 1292 (quoting *G.M. Leasing Corp. v. United States*, 429 U.S. 338, 354 (1977)) (emphasis added). The *Colonnade-Biswell* exception did not apply because it is based largely on the diminished expectation of privacy in a closely-regulated industry, *see Burger*, 482 U.S. at 700, and the physician in *Theramatic I* was not closely regulated by the FDA.

The district court, however, accepted Argent's interpretation of *Theramatic I*, concluding that "[a]lthough a well-defined scheme for inspecting pervasively regulated businesses may survive Fourth Amendment scrutiny, the protection against unreasonable searches and seizures may nevertheless prevent government agents from returning to conduct a particularized search and seizure without first obtaining an ordinary warrant." The District Court held that *Theramatic I* forbade agents from searching "a particular business to seize particular, identified chemicals and drugs."

Theramatic I's reference to a particularized search, however, was made to point out that the search conducted there was not an administrative search similar to those designed to insure sanitary housing conditions, *see*

Camara v. Municipal Court, 387 U.S. 523 (1967), or workplace safety, *see Marshall v. Barlow's, Inc.*, 436 U.S. 307 (1978); that was not what the FDA was doing. But a wholly separate point (which we thought was even clearer) was that the physician was not "closely regulated" by the FDA and therefore was not subject to the *Colonnade-Biswell* exception. *Theramatic I*, 641 F.2d at 1295.

Thus it is the invasion of privacy, not the particularity of the seizure, that is the relevant difference between Argent's case and *Theramatic I* for purposes of the *Colonnade-Biswell* exception. Argent, being closely regulated by the FDA, has a diminished expectation of privacy that was not violated by the seizure. We attach no significance to the fact that the FDA "returned" to execute its *in rem* warrant some time after its last inspection. If a random, unannounced inspection does not violate Argent's Fourth Amendment right of privacy, we see no reason why the unannounced execution of a warrant under the Supplemental Rules would do so. The seizure is from the premises of a closely regulated manufacturer and is conducted within the regulatory scheme in the manner Congress has authorized. There is no need to brigade the seizure with an inspection in order to legitimize it; Argent's expectation of privacy has not been violated.

VI. Conclusion

Under the *Colonnade-Biswell* exception to the Fourth Amendment, Argent had a "reduced expectation of privacy." *Burger*, 482 U.S. at 702. As a consequence, the seizure of Argent's drugs from its premises pursuant to a

warrant issued in accordance with 21 U.S.C. § 334 and Supplemental Rule C did not violate the Fourth Amendment.

REVERSED.

APPENDIX B

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES, Plaintiff, v. VARIOUS ARTICLES OF DRUG, Defendant.	CASE NO. C94-112OC ORDER ON MOTION TO QUASH WARRANT AND RETURN PROPERTY (Filed Dec. 15, 1994)

This matter comes before the Court on the motion of claimant Argent Chemicals Laboratories, Inc., for an order quashing the *in rem* arrest warrant and directing the government to return the seized articles.

I. BACKGROUND

Agents of the Food and Drug Administration inspected Argent's facilities several times in the summer and fall of 1993, and in May of 1994. The final FDA inspection occurred on May 9, 1994. The FDA cited Argent for certain deficiencies and requested that corrections be made. Argent states that it then made the corrections as requested.

On August 11, 1994, FDA agents and U.S. Marshals seized various drugs and chemicals from Argent, acting on the authority of an arrest warrant signed by Nealann Shari, Deputy Clerk of the District Court. There are no

probable cause determination or judicial review of any kind prior to the issuance of the warrant.

II. ANALYSIS

This forfeiture action arises under 21 U.S.C. § 334, which authorizes the seizure and forfeiture of, among others things, adulterated drugs. The statute provides that "the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty." *Id.*

Rule C of the Supplemental Rules for Certain Admiralty and Maritime Claims provides that

> [i]n actions by the United States for forfeitures for federal statutory violations, the clerk, upon filing of the complaint, shall forthwith issue a summons and warrant for the arrest of the vessel or other property without requiring a certification of exigent circumstances.

Argent argues that the search and seizure of its property pursuant to Rule C violated the Fourth Amendment, because the warrant was not subject to a probable-cause determination by a district judge.

A

The Fourth Amendment prohibits "unreasonable searches and seizures." Warrantless searches of private property, "except in certain carefully defined classes of cases," are unreasonable. *Camara v. Municipal Court*, 387

U.S. 523, 87 S. Ct. 1727, 1731(1967). Because "[t]he businessman, like the occupant of a residence, has a constitutional right to go about his business free from unreasonable official entries upon his private commercial property," *See v. City of Seattle*, 387 U.S. 541, 87 S. Ct. 1737, 1739 (1967), the warrant clause "protects commercial buildings as well as private homes," *Marshall v. Barlow's Inc.*, 436 U.S. 307, 98 S. Ct. 1816, 1819 (1978).

The Supreme Court has carved out exceptions to the warrant requirement for "pervasively regulated businesses" and for "closely regulated industries long subject to close supervision and inspection." *Barlow's*, 98 S. Ct. at 1820-21 (citations and internal quotations omitted). In *Colonnade Catering Corp. v. United States*, 397 U.S. 72, 90 S. Ct. 774, 777 (1970), the Court acknowledged Congress' "broad authority to fashion standards of reasonableness for searches and seizures" in the liquor industry, "long subject to close supervision and inspection." Then, in *United States v. Biswell*, 406 U.S. 311, 92 S. Ct. 1593 (1972), the Court held that warrantless inspections of a firearms dealership, conducted pursuant to a statutory inspection scheme, did not offend the Fourth Amendment. But the Court has maintained that these cases are exceptions to the general rule,

> represent[ing] responses to relatively unique circumstances. Certain industries have such a history of government oversight that no reasonable expectation of privacy could exist for a proprietor over the stock of such an enterprise. Liquor (*Colonnade*) and firearms (*Biswell*) are industries of this type; when an entrepreneur embarks upon such a business, he has voluntarily chosen

> to subject himself to a full arsenal of governmental regulation.

Barlow's, 98 S. Ct. at 1821 (citations omitted). The Court went on to say that "[t]he element that distinguishes these enterprises from ordinary businesses is a long tradition of close government supervision, of which any person who chooses to enter such a business must already be aware." *Id.*

More recently, the Court has upheld warrantless inspection schemes involving coal mines, *Donovan v. Dewey*, 452 U.S. 594, 101 S. Ct. 2534 (1981), and automobile junkyards, *New York v. Burger*, 482 U.S. 691, 107 S. Ct. 2636 (1987). In *Burger*, the Court clarified that warrantless inspections of pervasively regulated businesses are reasonable only if three criteria are met. First, there must be a substantial government interest that informs the regulatory scheme. *Burger*, 107 S. Ct. at 2644. Second, the warrantless inspections must be necessary to further the regulatory scheme. *Id.* And third, the inspection program, in terms of the certainty and regularity of its application, must provide a constitutionally adequate substitute for a warrant. *Id.*

B

The government argues that the *Colonnade-Biswell* exception to the warrant requirement applies here. Specifically, the government urges that the drug-manufacturing industry is so closely regulated that owners of drug factories have a lesser expectation of privacy which must give way to the government's substantial interest in protecting the public from adulterated drugs. Therefore, the

government reasons, the *in rem* arrest procedure of Supplemental Rule C does not violate any Fourth Amendment protection afforded the owners of a drug factory.

The government relies heavily on the Eighth Circuit's decision in *United States v. Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532 (8th Cir. 1981), *cert. denied*, 445 U.S. 1016 (1982). In *Jamieson-McKames* the court held that the warrantless inspection procedure of the Food, Drug, and Cosmetic Act, set out at 21 U.S.C. § 374, does not violate the Fourth Amendment because it fails within the *Colonnade-Biswell* exception. The government also cites *Founding Church of Scientology v. United States*, 409 F.2d 1146 (D.C. Cir.), *cert. denied*, 396 U.S. 963 (1969), which held that the procedure in admiralty, employed to seize E-meters from the Church of Scientology, did not violate the Fourth Amendment.[1]

Contrary to the government's assertion, neither of these cases is directly on point. *Jamieson-McKames* stands for the proposition that § 374, the inspection provision of the FD&C Act, does not offend the Fourth Amendment. *Jamieson-McKames*, 651 F.2d at 538 (holding that "inspections authorized by § 374 are 'reasonable' and therefore not inconsistent with the Fourth Amendment"). The case does not address § 334, the provision related to arrests *in rem*, except in the context of the applicable probable-cause standard. *Id.* at 651 F.2d at 540-41 & n.17. Although

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[1] The government also cites *United States v. Articles of Hazardous Substance*, 588 F.2d 39 (4th Cir. 1978). That case is inapposite because it involved commercial premises open to the public, and therefore presented no invasion of privacy. *Id.* at 43 n.1.

the agents in *Jamieson-McKames* obtained the *in rem* arrest warrants pursuant to Rule C, *see id.* at 540 & n.17, it appears that defendants challenged the seizures only on the basis that "the application for the warrant for inspection did not comply with traditional probable-cause standards." *Id.*

Similarly, in *Founding Church of Scientology*, the court did not specifically reach the question of whether an *in rem* arrest warrant issued by a court clerk would meet Fourth Amendment standards, because there, "[t]he libel was subject to scrutiny by a United States District Judge, and it was only after his review and by court order that the warrant issued." *Founding Church of Scientology*, 409 F.2d at 1150. The court's other statements to the effect that the Fourth Amendment did not necessarily require a "showing of probable cause before a magistrate" in the contest of civil attachments under the rules of admiralty is *dicta*. *Id.*

C

The Ninth Circuit, on the other hand, has specifically addressed the issue of whether a court clerk may, consistent with the Fourth Amendment, issue a warrant for an arrest *in rem* under § 334. In *United States v. Device, Labeled "Theramatic"*, 641 F.2d 1289 (9th Cir. 1981), federal agents entered a doctor's office and seized a diathermy machine alleged to be misbranded. The agents acted on the authority of an arrest warrant issued by the clerk of the court. The Ninth Circuit concluded:

> We hold that absent exigent circumstances, entrance into homes and offices to seize items

> alleged to violate the Food, Drug, and Cosmetic Act must comply with the basic requirements of the Fourth Amendment: the verified complaint on which the warrant authorizing seizure is based must provide probable cause to believe that the article to be seized violates the act, and the complaint must be scrutinized by a detached, independent official, empowered to decide whether probable cause does exist, before the warrant is issued.

Id. at 1295. In so holding, the court explained that because "the government had a specific target in mind," the cases involving random inspections to enforce statutory standards did not apply. *Id.* at 1294 (citing *Barlow's* 98 S. Ct. 1816, and *Camera*, 87 S. Ct. 1727). The court also rejected the argument that the search fell within the *Colonnade-Biswell* exception because "the search at issue here was not part of any statutory program to inspect physicians' offices – the same seizure procedure could have been used against misbranded devices no matter where they were found." *Id.* at 1295.

Thus, there is an important distinction between *Theramatic* and the *Colonnade-Biswell* line of cases. *Theramatic* does not address the question of whether the general inspection scheme of § 374 violates the Fourth Amendment, the constitutionality of which would obviously be subject to analysis under *Colonnade-Biswell*. *See Jamieson-McKames*. *Theramatic* does, however, directly address whether *in rem* arrest warrants may constitutionally be issued pursuant to § 334 and Supplemental Rule C. Although a well-defined scheme for inspecting pervasively regulated businesses may survive Fourth Amendment scrutiny, the protection against unreasonable

searches and seizures may nevertheless prevent government agents from returning to conduct a particularized search and seizure without first obtaining an ordinary warrant.[2] *Cf. United States v. Articles of Drug Consisting of Following: Undetermined Quantity of 100-Capsule Bottles, etc.*, 568 F. Supp. 1182 (N.D. Cal. 1983).

Theramatic is binding authority directly on point. The agents in this case had previously conducted administrative inspections pursuant to § 374. The constitutionality of these inspections is not at issue here. Based on their conclusion that Argent was in violation of the Act, the agents obtained the *in rem* arrest warrant to search a particular business to seize particular, identified chemicals and drugs. The arrest warrant was issued, pursuant to § 334 and Supplemental Rule C, by a deputy clerk who did not, indeed could not, review the government's allegations to determine if there was cause to seize the items. This is precisely what the Ninth Circuit forbade in *Theramatic*.

The government argues that *Theramatic* is distinguishable on the ground that the search there involved a doctor's office, not a drug factory. The Court is unpersuaded by this distinction. First, the Supreme Court decisions interpreting the Fourth Amendment's reach into the commercial realm do not make a distinction between a

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[2] It is worth noting in this context that during a warrantless inspection under § 374, the agents may take samples. They may proceed to seize and forfeit items only under § 334. There is nothing unusual about the suggestion that the seizure under § 334 requires greater safeguards than the inspection under § 374.

business or professional office and a factory. Rather, the Court has simply stated that the Fourth Amendment protects "private commercial property," *See*, 87 S. Ct. at 1739, and "commercial buildings." *Barlow's*, 98 S. Ct. at 1819. Second, the government's approach would tend to create a confusing body of case law giving law enforcement officers unreliable standards for determining whether and when to obtain judicially-authorized warrants.

Finally, the government cites a number of district court decisions authorizing the *in rem* arrest procedure in the context of violations of the FD&C Act. *E.g., United States v. Articles of Drug . . . WANS*, 526 F. Supp. 703, 706 (D.P.R. 1981); *United States v. Undetermined quantities of . . . blue-green algae*, 1983 WL 1076 (D. Or. 1983). The Court is not free to follow the reasoning of other district courts in the face of countervailing Ninth Circuit authority.

III. CONCLUSION

The Ninth Circuit has held unambiguously that agents seeking to enter a business office to seize items alleged to violate the Food, Drug, and Cosmetic Act must comply with the Fourth Amendment by obtaining a warrant based upon probable cause and authorized by a detached judicial officer. Argent Chemical's motion to quash is therefore GRANTED. The government is hereby ORDERED to return the seized property to Argent Chemicals.

SO ORDERED this 15th day of Dec., 1994.

/s/ JOHN C. COUGHENOUR
The Honorable John C. Coughenour
United States District Judge

APPENDIX C

Pertinent Provisions of the Food, Drug and Cosmetic Act

21 U.S.C. 334(a):

§ 334 Seizure

(a) Grounds and jurisdiction

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or

would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(b) Procedure; multiplicity of pending proceedings

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties.

If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

APPENDIX D

Supplemental Rules for Certain Admiralty and Maritime Claims Rule C. Actions in Rem: Special Provisions

(1) WHEN AVAILABLE. An action in rem may be brought:

(a) To enforce any maritime lien;

(b) Whenever a statute of the United States provides for a maritime action in rem or a proceeding analogous thereto.

Except as otherwise provided by law a party who may proceed in rem may also, or in the alternative, proceed in personam against any person who may be liable.

Statutory provisions exempting vessels or other property owned or possessed by or operated by or for the United States from arrest or seizure are not affected by this rule. When a statute so provides, an action against the United States or an instrumentality thereof may proceed on in rem principles.

(2) Complaint. In actions in rem the complaint shall be verified on oath or solemn affirmation. It shall describe with reasonable particularity the property that is the subject of the action and state that it is within the district or will be during the pendency of the action. In actions for the enforcement of forfeitures for violation of any statute of the United States the complaint shall state the place of seizure and whether it was on land or on navigable waters, and shall contain such allegations as may be required by the statute pursuant to which the action is brought.

APPENDIX E

§ 374 Inspection

(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions. (1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs or restricted devices which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by

paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 505(i) or (k), section 507(d) or (g), section 519, or 520(g) [21 USCS § 355(i) *or* (k), § 357(d) or (g), § 360i, or § 360j(g)], and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) [21 USCS § 355(j)]). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Supreme Court, U.S.
FILED
FEB 14 1997
CLERK

(2)

No. 96-766

In the Supreme Court of the United States

OCTOBER TERM, 1996

ARGENT CHEMICAL LABORATORIES, INC., ETC.,
PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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19 pp

QUESTION PRESENTED

Whether the seizure of veterinary drugs pursuant to a warrant for arrest *in rem* issued by the district court in conformity with the procedures outlined in the Federal Food, Drug, and Cosmetic Act and the Supplemental Rules for Certain Admiralty and Maritime Claims, after an uncontested warrantless inspection of petitioner's premises, violates the Fourth Amendment.

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UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A14) is reported at 93 F.2d 572. The opinion of the district court (Pet. App. B1-B10) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on August 16, 1996. The petition for a writ of certiorari was filed on November 14, 1996. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (FDCA) prohibits persons from adulterating medical or veterinary drugs in interstate commerce, and from selling or receiving such drugs that have been adul-

terated. 21 U.S.C. 331(a)-(c). The FDCA expressly provides that any article of a drug that has been adulterated "shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States * * * within the jurisdiction of which the article is found." 21 U.S.C. 334(a)(1). The statute further states that "[t]he article * * * proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty." 21 U.S.C. 334(b).

The Supplemental Rules for Certain Admiralty and Maritime Claims (Supplemental Rules) "apply to the procedure in statutory condemnation proceedings analogous to maritime actions in rem, whether within the admiralty and maritime jurisdiction or not." Admiralty Suppl. R. A. Under the Supplemental Rules, an action in rem may be brought "[w]henever a statute of the United States provides for a maritime action in rem or a proceeding analogous thereto." Admiralty Suppl. R. C(1)(b). Such an action is commenced by a complaint, which must "be verified on oath or solemn affirmation," and which must "describe with reasonable particularity the property that is the subject of the action." Admiralty Suppl. R. C(2).

The Supplemental Rules require prior judicial review of the complaint before the issuance of a warrant for arrest of the property subject to the action, "[e]xcept in actions by the United States for forfeitures for federal statutory violations." Admiralty Suppl. R. C(3). Where an action by the United States for a forfeiture for a federal statutory violation is involved,

the Supplemental Rules explicitly provide that the "the clerk, upon filing of the complaint, shall forthwith issue a summons and warrant for the arrest of the vessel or other property without requiring a certification of exigent circumstances." *Ibid.*

2. Petitioner Argent Chemical Laboratories is engaged in the business of manufacturing and repackaging veterinary drugs. Pet. App. A2. On July 29, 1994, as the result of several FDA inspections of petitioner's facilities, the United States obtained a warrant for arrest of certain of petitioner's drugs from the deputy clerk of the United States District Court for the Western District of Washington, in accordance with the Supplemental Rules. Pet. App. A2-A3; Pet. 3.

Petitioner filed a motion to quash the government's warrant on the ground that the seizure of its drugs without a prior judicial warrant violated the Fourth Amendment. Pet. App. A3. The district court granted petitioner's motion, concluding that, notwithstanding the FDCA and the Supplemental Rules, the government was required by the Fourth Amendment to "obtain[] a warrant based upon probable cause and authorized by a detached judicial officer." *Id.* at B9. It therefore ordered the seized drugs returned to petitioner. *Ibid.*

3. The court of appeals reversed. Pet. App. A1-A14. After reviewing this Court's cases dealing with Fourth Amendment protections applicable to "closely regulated" businesses, see *Colonnade Catering Corp.* v. *United States*, 397 U.S. 72 (1970); *United States* v. *Biswell*, 406 U.S. 311 (1972), the court concluded that the seizure of petitioner's drugs did not violate the Fourth Amendment. Pet. App. A14.

The court first reviewed the extensive regulations applicable to the preparation, packaging and promotion of animal drugs (Pet. App. A6-A7), and concluded that the veterinary drug industry is "closely regulated" under *Colonnade-Biswell*. The court also found that the other criteria for application of the *Colonnade-Biswell* doctrine had been met: (1) the government has a "substantial interest" in regulating the safety and effectiveness of animal drugs, (2) warrantless searches and seizures further the regulatory scheme by deterring violations of regulatory requirements and removing nonconforming products from the marketplace, and (3) by advising the commercial owner that the premises are subject to search, while at the same time limiting the scope of that search, the statute and the Supplemental Rules "provide a constitutionally adequate substitute for a warrant." *Id.* at A8-A9. See generally *New York* v. *Burger*, 482 U.S. 691, 701-702 (1987).

The court of appeals rejected as "untenable" petitioner's contention that the *Colonnade-Biswell* doctrine applies only to inspections and not to seizures, observing that decisions of this Court have applied the exception to "seizures of contraband discovered during the unwarranted inspections," and have "approved the use of evidence seized in the course of the inspection." Pet. App. A10. The court also "attach[ed] no significance" to the fact that the warrant for arrest of petitioner's drugs was executed "some time after" the FDA's last inspection of petitioner's premises. *Id.* at A13. "If a random, unannounced inspection does not violate [petitioner's] Fourth Amendment rights of privacy," the court stated, "we see no reason why the unannounced execution of a warrant under the Supplemental Rules

would do so." *Ibid.* In short, the court concluded, because the seizure of petitioner's drugs was from "the premises of a closely regulated manufacturer" and was "conducted within the regulatory scheme in the manner Congress has authorized," there was "no need to brigade the seizure with an inspection in order to legitimize it." *Ibid.*

ARGUMENT

The decision below is correct and does not conflict with the decision of any other court of appeals. This case thus does not warrant further review.

1. Although the Fourth Amendment's protections apply to commercial as well as residential premises, see, *e.g.*, *See* v. *City of Seattle*, 387 U.S. 541, 545-546 (1967), "a business, by its special nature and voluntary existence, may open itself to intrusions that would not be permissible in a purely private context." *G.M. Leasing Corp.* v. *United States*, 429 U.S. 338, 353 (1977). Thus, a judicial warrant is not always required when the government seeks to conduct a search of a business "long subject to close supervision and inspection," *Colonnade Catering Corp.* v. *United States*, 397 U.S. 72, 77 (1970), or that has been "pervasively regulated." *United States* v. *Biswell*, 406 U.S. 311, 316 (1972).

The so-called *Colonnade-Biswell* exception to the Fourth Amendment's judicial warrant requirement derives from the fact that owners of commercial property subject to comprehensive government supervision have a "reduced expectation of privacy," *New York* v. *Burger*, 482 U.S. 691, 702 (1987), and "an inspection program may in some cases be a necessary component of federal regulation." *Donovan* v. *Dewey*, 452 U.S. 594, 599 (1981). Under the exception,

the government may conduct a search of a "closely regulated" commercial business without a warrant if three criteria are met. *Burger*, 482 U.S. at 702. First, the regulatory scheme authorizing the warrantless inspection must be supported by a "substantial" government interest. *Ibid.* Second, warrantless inspections must be "necessary to further [the] regulatory scheme." *Ibid.* Third, "the statute's inspection program, in terms of the certainty and regularity of its application, [must] provid[e] a constitutionally adequate substitute for a warrant." *Id.* at 703.

The *Colonnade-Biswell* exception applies to seizures as well as searches, as the court of appeals recognized. Pet. App. A10. *Colonnade* itself was a suit for return of "seized liquor," 397 U.S. at 72, and this Court there took care to emphasize Congress's "broad authority to fashion standards of reasonableness for *searches and seizures*" in the liquor industry. *Id.* at 77 (emphasis added). Similarly, in *Biswell*, the issue involved the admissibility of two unlicensed firearms that had been seized during a warrantless search. See 406 U.S. at 312. Moreover, the Fourth Amendment is concerned with "reasonable expectations of privacy." *Katz* v. *United States*, 389 U.S. 347, 361 (1967) (Harlan, J., concurring); see *Burger*, 482 U.S. at 699-701. In the present context, the intrusion on an owner's privacy expectations is no greater from the government's seizure of commercial goods than from the government's inspection of the same items. See *Minnesota* v. *Dickerson*, 508 U.S. 366, 377 (1993) ("The seizure of an item whose identity is already known occasions no further invasion of privacy"); see also *Skinner* v. *Railway Labor Executives' Ass'n*, 489 U.S. 602, 618 n.4 (1989) ("It is not necessary to our

analysis * * * to characterize the taking of * * * samples as a seizure * * *, for the privacy expectations protected by this characterization are adequately taken into account by our conclusion that such intrusions are searches").[1]

2. The *in rem* seizure of petitioner's drugs did not violate the Fourth Amendment under the *Colonnade-Biswell* principles. Businesses engaged in the manufacture, packaging and storage of human and animal drugs plainly are "closely regulated" within the meaning of the *Colonnade-Biswell* exception. *United States* v. *Jamieson-McKames Pharmaceuticals, Inc.*, 651 F.2d 532, 537 (8th Cir. 1981), cert. denied, 455 U.S. 1016 (1982). The FDCA, as well as the FDA's regulations promulgated thereunder, regulate "virtually every phase of the drug industry * * * from packaging, labeling and certification of expiration dates, to prior FDA approval before new drugs can be marketed." 651 F.2d at 537 (footnote omitted). See, *e.g.*, 21 U.S.C. 351(a) (regulating manufacture), 21 U.S.C. 351(b) (regulating strength and purity), 21 U.S.C. 352(a), (b), (f), (g), (h) and (p) (packaging and labeling), 21 U.S.C. 355 (new drug approvals); 360b

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[1] Of course, a seizure affects a claimant's *possessory* interests in a way that an inspection does not. See *Horton* v. *California*, 496 U.S. 128, 133 (1990). But a claimant's possessory interests in alleged contraband do not override the public's interest in having potentially hazardous or ineffective drugs removed temporarily from the stream of commerce. See *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 601 (1950). And the claimant is fully protected against being permanently dispossessed of its goods by the statutorily-protected opportunity to contest the government's action for permanent forfeiture. See 21 U.S.C. 334; Admiralty Suppl. R. C; *Ewing*, 339 U.S. at 598.

(new animal drug approvals); 21 C.F.R. Pts. 200-599. As a company engaged in the manufacture, packaging and storage of veterinary drugs, petitioner operates in a business long subject to pervasive and comprehensive government regulation. Pet. App. A7-A8 & n.3

There can also be little doubt that the regulatory scheme governing the drug industry furthers a substantial government interest. See *Burger*, 482 U.S. at 702. Drugs intended to treat diseases in human beings that are manufactured, packaged or stored without proper safeguards pose an obvious health and safety risk to those who use them, for in the absence of compliance with regulatory standards, there can be no assurance that the drug is safe for its intended use, or "has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 U.S.C. 351(a)(2)(B). The government similarly has a substantial interest in the safety and effectiveness of animal drugs since unsafe or ineffective animal drugs pose a serious risk to the health and safety of the animals for whom they are prescribed. Indeed, unsafe or ineffective animal drugs may pose a significant risk to human health, when the diseases for which they are prescribed affect animals destined for human consumption. See *United States* v. *9/1 KG Containers*, 854 F.2d 173, 174 (7th Cir. 1988), cert. denied, 489 U.S. 1010 (1989). In short, as the court of appeals concluded, whether the government's interest in the safety and effectiveness of animal drugs "is human health, economic health, or both * * * it is substantial." Pet. App. A8.

The authority to seize adulterated goods without a judicial warrant is also a necessary aspect of the regulatory scheme governing the preparation, pack-

aging and storage of human and animal drugs. See *Burger*, 482 U.S. at 709-710. A drug that has been improperly manufactured, packaged, or stored, or as to which there is no documentation that regulatory standards have been followed, poses an obvious risk to the physical—and economic—health and safety of those who would use it. Eliminating that threat is not simply a matter of determining that a regulatory violation has occurred, and imposing a penalty or other sanction on the manufacturer. To eliminate the threat to the public the offending drugs must be removed from the marketplace. See Pet. App. A9. Drugs are easily sold, and there may be few means—apart from strict compliance with the FDCA's requirements—for a consumer to know whether the drug he or she has purchased is safe and effective for its intended use. See *United States* v. *Dotterweich*, 320 U.S. 277, 285 (1943).

Finally, the FDCA and the Supplemental Rules provide a "constitutionally adequate substitute for a warrant." *Burger*, 482 U.S. at 711. See Pet. App. A9. The FDCA expressly informs those who manufacture, package or store human or animal drugs that adulterated or misbranded drugs "shall be liable to be proceeded against * * * on libel of information and condemned" in federal district court, 21 U.S.C. 334(a)(1), in accordance with procedures that "conform, as nearly as may be, to the procedure in admiralty." 21 U.S.C. 334(b). Thus, petitioner could not "help but be aware" that its drugs would be subject to seizure if they proved adulterated. *Dewey*, 452 U.S. at 600; see also *Skinner*, 489 U.S. at 622. The FDCA also "narrowly define[s]" the scope of the seizures it authorizes. See *Burger*, 482 U.S. at 711. Government officials are empowered to seize only those drugs that

are "adulterated or misbranded," 21 U.S.C. 334(a)(1), terms that the statute defines in detail. See, *e.g.*, 21 U.S.C. 351, 352. Moreover, consistent with the Fourth Amendment's admonition that "the persons or things to be seized" must be "particularly described," U.S. Const. Amend. IV, the Supplemental Rules require that the complaint that commences an action to enforce a forfeiture for federal statutory violations "shall describe with reasonable particularity the property that is the subject of the action and state that it is within the district or will be during the pendency of the action," as well as stating "the place of seizure." Admiralty Suppl. R. C(2).[2] Like the Fourth Amendment, moreover, the Supplemental Rules provide that the government's complaint for forfeiture "shall be verified on oath or solemn affirmation." *Ibid.* Finally, a decision to commence a forfeiture action is not lightly undertaken. As the court of appeals recognized, in most cases one of FDA's 21 district offices, the appropriate FDA Center in headquarters, the agency's Office of Enforcement, as well as the Office of Chief Counsel and the Department of Justice all review the merits of a case before a seizure is recommended. Pet. App. A9-A10 (citing *FDA Regulatory Practices Manual*, Ch. 6, at 173-185 (Aug. 1995)). See *Ewing*, 339 U.S. at 599. "The discretion of Government officials to determine what" items to seize "is thus directly curtailed by the regulatory scheme." *Dewey*, 452 U.S. at 605; see also *National*

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[2] See also Admiralty Suppl. R. E(2)(a) (requiring the complaint to "state the circumstances from which the claim arises with such particularity that the defendant or claimant will be able, without moving for a more definite statement, to commence an investigation of the facts and to frame a responsive pleading").

Treasury Employees Union v. *Von Raab*, 489 U.S. 656, 667 (1989).

3. Petitioner does not dispute that it engages in a business that is so closely and comprehensively regulated by the federal government as to fall within the *Colonnade-Biswell* exception. Nor does petitioner assert that the warrantless inspections of its property violated the Constitution or that the government's actions in obtaining an *in rem* arrest warrant were unauthorized by the FDCA. Petitioner's sole argument is that the government's use of the FDCA's *in rem* arrest procedures in this case violated the Fourth Amendment because, in its view of the circumstances of this particular case, those procedures were not "necessary" to advance the government's interests under the FDCA, because government officials "waited 94 days" after the last regulatory inspection before seizing petitioner's drugs. Pet. 7.

The length of time elapsed between inspection and seizure in a particular case is, however, irrelevant to the issue of whether the government's actions are protected by the *Colonnade-Biswell* exception. "If a random, unannounced inspection does not violate [petitioner's] Fourth Amendment right of privacy," there is "no reason why the unannounced execution of a warrant under the Supplemental Rules would do so." Pet. App. A13. Nor is there reason to adopt a rule that would have the constitutional inquiry turn on a case-by-case analysis of whether federal officials will be able to obtain a judicial warrant without undermining administrative enforcement. Petitioner is willing to assume that "the regulatory *inspections* may have been necessary to further the regulatory scheme." Pet. 7 (emphasis added). Since this Court's decisions make clear that the government can seize

contraband discovered in the course of such inspections, see *Colonnade*, 397 U.S. at 72; *Biswell*, 406 U.S. at 312, there is no basis on which to conclude that a seizure subsequent to a warrantless inspection invades Fourth Amendment interests in a manner different from a seizure contemporaneous with a warrantless inspection. Compare *United States* v. *Jacobsen*, 466 U.S. 109, 120-121 (1984) (seizure of contraband by law enforcement was reasonable where prior to that seizure the owner's "privacy interest * * * had been largely compromised" by a private search); *United States* v. *Edwards*, 415 U.S. 800, 806-807 (1974). In short, as the court of appeals stated, there is no need to require the government "to brigade the seizure with an inspection in order to legitimize it." Pet. App. A13.

Petitioner also suggests that the subsequent seizure was unreasonable because it was "particularized." See Pet. 7, 9. But the fact that the government has identified specific items subject to seizure limits, rather than magnifies, the intrusion on petitioner's Fourth Amendment privacy expectations. Moreover, petitioner's suggestion is inconsistent with *Biswell*, which upheld the seizure of specific firearms discovered as the result of a warrantless government inspection. *Biswell*, 406 U.S. at 312-313. Indeed, it would be odd to conclude that the government does not need a judicial warrant to enter into and inspect a regulated commercial establishment when it has *no* particular reason to suspect noncompliance with regulatory obligations, but that it must obtain such a warrant when, as here, it has information that specific items are being held in violation of regulatory requirements—especially in light of the Fourth Amendment's stated preference for particularity in

government searches and seizures. U.S. Const. Amend. IV.

4. Petitioner also contends (Pet. 11-12) that the decision below conflicts with the Tenth Circuit's reasoning in *Winters* v. *Board of County Commissioners*, 4 F.3d 848 (1993), cert. denied, 114 S. Ct. 1539 (1994), which invalidated a police seizure of a stolen ring from an Oklahoma pawn shop. The *Winters* court, however, based its decision on its conclusion that the seizure of the ring was the result of "pretextual" inspection of the shop, which failed to give the police "a lawful right of access" to the seized property. 4 F.3d at 854; compare *Burger*, 482 U.S. at 717 n.27.

In this case, by contrast, it is undisputed that the seizure of petitioner's drugs resulted from a lawful administrative search of petitioner's premises, pursuant to the FDCA and the Supplemental Rules, which—unlike the Oklahoma statute in *Winters*—expressly authorize seizures of adulterated drugs without a judicial warrant. See 21 U.S.C. 334. In addition, the consequences from the delayed seizure of a ring are, to say the least, decidedly different from those presented by the failure to seize drugs that may be unfit or unsafe for their intended use.[3]

Petitioner also contends that the decision of the court of appeals conflicts with its prior decision in

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[3] The concerns expressed by the Tenth Circuit in *S & S Pawn Shop, Inc.* v. *City of Del City*, 947 F.2d 432, 441 (1991) (see Pet. 11)—a decision that actually upheld the facial constitutionality of the Oklahoma pawnshop inspection scheme—similarly related to allegations that specific pawnshop inspections "were conducted not as part of a pre-planned and dispassionate administrative procedure but instead pursuant to direct criminal suspicion."

United States v. *Device, Labeled "Theramatic"*, 641 F.2d 1289 (9th Cir. 1981) (*Theramatic I*), which invalidated the warrantless seizure of an allegedly misbranded medical device from a doctor's office under the FDCA. As the court of appeals explained, however, the seizure in *Theramatic I* "was effectuated by an impermissible invasion of the * * * right of privacy" of a physician whose business (unlike that of petitioner) was "not closely regulated by the FDA"; thus "[t]he *Colonnade-Biswell* exception did not apply" at all. Pet. App. A11-A12. And even if there were an intracircuit conflict within the Ninth Circuit, the matter would be more appropriate for the court of appeals, rather than for this Court, to resolve. See *Wisniewski* v. *United States*, 353 U.S. 901, 902 (1957).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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